
International Standard



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Dairy plant — Hygiene conditions — General guidance on inspection and sampling procedures

Usine laitière — Conditions sanitaires — Directives générales pour les méthodes de contrôle et d'échantillonnage

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8086 was prepared by Technical Committee ISO/TC 34, *Agricultural food products*.

NOTE -- The text of this International Standard has been developed jointly with the International Dairy Federation (IDF) and the Association of Official Analytical Chemists (AOAC) and will also be published by these organizations.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Dairy plant — Hygiene conditions — General guidance on inspection and sampling procedures

0 Introduction

The principal reason for checking plant hygiene is to ensure that the plant will not contaminate the product; however, if contamination has taken place, it is possible to discover where in the circuit bacteriological infection, chemical contamination or contamination from filth has taken place. Such checks will be necessary not only to ensure quality control requirements within the plant but also to ensure compliance of products with legal requirements. Also, the checks give information on the checking and sampling procedures used to endorse the practices adopted to ensure cleanliness of the plant.

There are three types of checks on the effectiveness of cleaning and disinfection for which sampling might be performed:

- a) checking all contact surfaces which have to be cleaned after and shortly before the production process, and checking re-usable product containers (bottles, moulds, etc.) which have to be cleaned and which will hold the finished product intended for sale;
- b) indirect checking on solutions or methods used for cleansing; such checks will concern principally the different operations carried out to ensure that optimum cleanliness is maintained;
- c) checking the raw materials or semi-finished products in the course of preparation or of finished products; in practice, such checks give a good idea of the quality of cleansing but they are ancillary to the quality of the raw material used and, in some cases, to the standard of hygiene of the operators of the plants.

1 Scope and field of application

This International Standard lays down general guidelines for inspection and sampling procedures to be employed to check the effectiveness of cleaning and disinfection methods used in dairy plants and receiving stations, including milk-collection tankers.

It deals with

- visual inspection;
- sampling from plant surfaces (product line, bottle washing equipment, containers, etc.);
- re-usable product containers;
- air;

- sampling of water and aqueous solutions other than those added to the product;
- sampling of raw materials and products.

It does not deal with equipment normally installed in farms, for example milking machinery or refrigerated bulk milk tanks, nor does it deal with the equally important areas of health and hygiene of personnel, factory environment, internal arrangement of the factory, methods of cleaning, packaging materials brought in new from outside (paper, cardboard, plastic, new bottles, etc.), food ingredients and additives, selection of number of units and treatment of the sample in the laboratory.

The need for sampling should have been considered in the design of plant. It is important that any devices which are included to enable samples to be taken are so designed and fitted that their use results in representative samples being obtained without any adverse effect on the hygiene condition of the plant (for example by introducing dead spots in cleaning circuits). Such design is outside the scope of this International Standard.

2 Reference

ISO 707, *Milk and milk products — Methods of sampling*.

3 General instructions

3.1 The demands for effectiveness of cleansing operations vary from plant to plant depending on management supervision, quality control requirements and type of production undertaken.

3.2 A cleansing control should not be based solely on the results of microbiological tests even if such checks are clearly of prime importance; other checks such as visual inspection, smell and touch, chemical and/or physical analysis and intelligent interpretation of records, are important in order not to overlook such factors as visible residues, malfunction of equipment, cleaning residues and corrosion.

3.3 Sampling for microbiological examination should be carried out only by personnel trained in sampling for this purpose.

3.4 The frequency of sampling depends essentially on the type of manufacture, the means of checking available to the organization, and the costs acceptable to the organization in carrying out the checking. In theory, a check should be carried

out after each cleansing or at a stated interval when cleansing is continuous during a production run (for example the case of a bottle washer), or just prior to recommencement of production. However, in practice, a number of checks are carried out to ensure the quality of the product and those checks provide an indirect check on the efficiency of cleansing. Thus, in practice, the checking of effectiveness of cleansing depends upon the quality assurance for the product, bearing in mind that a deterioration in quality is often due to failure in cleansing.

3.5 Generally, it can be said that the frequency of sampling should be determined by measuring the variability of the process, and comparing this with the risk of making non-standard product. The optimum solution to this problem requires a good quantitative knowledge of the process, an understanding of statistical quality control, and deliberate management decisions on the degree of risk which is acceptable.

3.6 It is essential that samples be accompanied by a report which identifies the place, date and time of sampling including any batch details and the name and designation of the sampling personnel. Where appropriate, the report shall include any relevant conditions or circumstances (for example the condition of the product containers and their surroundings, the temperature and relative humidity of the atmosphere, the method of sterilization of the sampling equipment, the location of the sampling point on the equipment, whether a preservative substance has been added to the samples) and any special information relating to the product being sampled (for example difficulty in achieving homogeneity of the product).

4 Inspection and sampling procedures

4.1 Visual inspection

4.1.1 An immediate and important impression of the cleanliness of a production line in a dairy plant can be obtained by visual inspection of the accessible parts of a plant. Included in this are all open containers and those closed with a lid, pipe fittings with their washers and gaskets, powder transport lines, air filters, parts which are operated by mechanical means (for example homogenizer, pistons, counting devices, stirrers and pumps) and re-usable product containers.

Visual inspection should allow detection of damage due to corrosion or erosion.

4.1.2 Visual inspection may be carried out using good natural or artificial light. Use of ultra-violet light should be resorted to only rarely because of the hazards involved. If ultra-violet light is used, it is more effective when the plant has been flushed with a fluoresceine dye; it is essential to cleanse the plant fully after use of such dyes.

Among many other confirmatory tests, the following may be applied to the surface under examination:

- a) a clean spatula may be used to scrape a surface carefully, to demonstrate the presence of a film or residues on improperly cleansed equipment;

- b) a piece of clean disposable muslin or tissue paper (moist, if desired) wiped over the inside of a can or over metal surfaces of other equipment will be soiled if the surface is improperly cleansed;

- c) no sign of fluorescence shall be detectable when the surface is carefully inspected with long wavelength (340 to 380 nm) ultra-violet light.

4.1.3 Stains, greasy residues, powder, or thin, hard films are indicative of inadequate cleansing conditions (for example inadequate times, chemical concentrations, flow velocities, etc.).

4.1.4 More substantial residues of product indicate poor training or discipline of cleaning personnel and/or inadequate circulation and/or leaking valves. Incomplete drainage of equipment increases the risk of contamination of product with chemicals and micro-organisms.

4.1.5 At intervals based on past observations and experience, product pumps and valves should be opened and seals and rubbers inspected, especially if products with a high viscosity are processed. This is important even when cleaning in place (CIP) is fully automated.

It is equally important to inspect at regular intervals the spray cleaning devices of the CIP system to ascertain whether they are working correctly.

If plant must be dismantled for checking, a rinse and disinfection cycle of the section of plant involved should follow reassembly.

4.1.6 Whenever visible residues are found in the equipment, it is essential that the cause be traced and measures be taken to remedy the fault. There is only limited value in a microbiological check of visually dirty equipment. Even if a sample happened to be satisfactory from a microbiological viewpoint, all other consequences of inadequate cleansing should be considered. However, determination of the main composition of the residue by chemical means is often more helpful when it comes to trouble-shooting.

4.1.7 Because visual inspection is the most rapid, cheapest and easiest method of examination, it should be carried out as often as possible, i.e. daily.

4.2 Sampling procedures for equipment

4.2.1 Contact surfaces

Although all product contact surfaces should be checked, many such surfaces are inaccessible and only limited facilities are available for sampling and checking the samples. Therefore, a rigorous selection will be necessary in practice. Particular attention should be given to those places which are difficult to cleanse, for example recesses, elbows, valves, shafts, stirrer paddles, gauges, probes.

NOTE — Sampling by fixed sampling cocks can often cause contamination of the sample and the results of the examination of such samples should be treated with reserve.

4.2.2 Times of checking

Appropriate times of checking will be after the cleansing and disinfection of the processing equipment and shortly before re-use of the processing equipment, to check that it has not become contaminated while out of operation.

4.2.3 Direct methods

The methods for the examination of contact surface infection are numerous, but in a dairy plant where all surfaces should be preferably disinfected if not sterilized, rinse and swab tests are preferred. Swab tests are used for plant and equipment where the rinsing technique is not applicable. Also used is the impression method, where a sterile medium is pressed on the contact surface, then placed and held in a sterile container and later incubated.

4.2.4 Indirect methods

As an alternative to direct methods (4.2.3), indirect methods can be used, either by sampling and examination of the final rinse water (this may include a check for absence of disinfecting agents) before the start of production or by sampling the initial processed product passed through the plant, and considering that as a "rinse" test of the process line.

In many manufacturing plants there are large sections of process plant which operate as a unit, and which it is desirable not to dismantle during routine operation and cleansing. Such plant is frequently cleansed automatically and may operate under automatic control (for example a UHT production line, tank filling, allocation and emptying). In these cases, dismantling for rinsing, swabbing or other direct methods can cause contamination and such methods should only be attempted when other evidence makes a special investigation necessary.

The preferred method for this type of plant is to sample the first product emerging from the process. However, periodic examination of equipment, as mentioned in 4.1.5, remains necessary.

4.2.5 Rinse method

For rinsing purposes, sterile rinsing solution (for example peptone/saline solution, quarter strength Ringer's solution) is normally dispensed in 500 ml quantities. This quantity will suffice for rinsing most pieces of equipment.

Do not use quantities smaller than 500 ml. If the utensil to be tested will not contain this quantity, leave the surplus rinsing solution in the bottle.

Thoroughly wet, as far as possible, the whole surface of the piece of equipment to be rinsed with the rinse solution. Agitation of the solution by rotary or other movement is necessary for dislodging organisms.

Return the rinse to the bottle. The solution should be examined immediately. If this is not possible, any delay shall be kept to a minimum and the sample shall be cooled quickly to not more than 4 °C and maintained between 0 and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 to 10 h).

NOTES

1 When halogen-releasing compounds, for example sodium hypochlorite, have been applied to any surface, add sodium thiosulfate to the rinsing solution before autoclaving, to give a concentration of 0,05 % (*m/m*).

Either 0,25 g of crystalline sodium thiosulfate ($\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$) or 1 ml of a 25 % (*m/m*) solution of crystalline sodium thiosulfate may be added to each 500 ml of rinsing solution.

2 Where dairy plant has received a final halogen-releasing rinse which cannot be completely drained off, the thiosulfate present in the bacteriological rinse solution may be insufficient to inactivate the residual halogen completely. Even a trace of residual halogen will reduce markedly the numbers of viable bacteria collected by the rinse from the plant and will give a lower count than would have been obtained with excess thiosulfate.

3 If a product containing a quaternary ammonium compound has been used for cleansing, add 5 ml of a sterile solution of a suitable inactivator to the rinse solution as soon as possible after rinsing. The inactivator is prepared by adding 4 % (*m/m*) of egg lecithin to a 6 % (*m/m*) aqueous solution of a suitable anhydrous condensation product of a long-chain fatty alcohol and ethylene oxide, and stirring the warm mixture until the lecithin is dissolved.

4.2.6 Swab method

4.2.6.1 General

This method is applicable to tanks, heat exchangers, large open surface coolers, butter churns, cheese vats, cocks, agitators, air vents, bottle fillers, etc. which cannot conveniently be rinsed. Swab tests can also provide useful local information in addition to the overall picture given by the rinse test.

4.2.6.2 Apparatus

4.2.6.2.1 Test tubes, of length 250 mm and diameter 25 mm, of heavy borosilicate glass or polypropylene.

4.2.6.2.2 Stainless steel wire, of suitable length (approximately 350 mm) and stiffness (diameter approximately 2,6 mm), formed into a loop at one end, and notched at the other end to hold the ribbon gauze (4.2.6.2.3).

4.2.6.2.3 Ribbon gauze, non-medicated, 50 mm wide.

4.2.6.3 Preparation of swab

The swab shall be 50 mm in length and shall consist of 175 mm of the gauze (4.2.6.2.3) wound round the notched end of the wire (4.2.6.2.2) and secured with thread.

4.2.6.4 Sterilization of swab

Place the swab in 25 ml of rinsing solution in a test tube, plug with cotton wool or a suitable rubber closure, cover the plug with greaseproof paper and sterilize by autoclaving at 121 ± 1 °C for 15 min. To obtain a final quantity of 25 ml of solution it is necessary to start initially with a larger quantity to allow for evaporation during autoclaving. The actual quantity shall be determined by trial and error with each individual autoclave.

NOTES

- 1 The rinsing solution should contain sodium thiosulfate or other suitable inactivator as indicated in notes 1 and 3 to 4.2.5.
- 2 Pre-sterilized disposable swabs may also be used, but the results obtained may not be comparable with those obtained according to 4.2.6.3.

4.2.6.5 Procedure

Where possible, examine an area of 900 cm². Press the swab with a rolling motion against the side of the test tube to remove excess liquid. Remove the swab and with heavy pressure rub back and forth over the area to be examined so that all parts of the surface are treated twice. The second rubbing should be at an angle of 90° to the first. Rotate the swab so that all parts of it make contact with the surface under test. Return the swab to the test tube and insert the cotton wool plug or rubber closure.

The swab should be examined immediately. If this is not possible, any delay shall be kept to a minimum and the tube with the swabs shall be cooled quickly to not more than 4 °C and maintained between 0 and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 to 10 h).

4.3 Sampling procedures for re-usable product containers

For re-usable product containers, a representative sample taken from each batch should be checked.

4.3.1 Techniques

Usually, the rinse technique (4.2.5) is used for sampling for re-usable product containers but, depending on the material, impression and swabbing methods can be used (see 4.2.3 and 4.2.6).

4.3.2 Washed cans (or churns)

4.3.2.1 General

The examination is designed to give information on the condition of washed cans. When the examination is carried out at the premises where the cans were washed, examine within an interval of not less than 30 min and not more than 1 h after washing.

Cans with open seams or containing milky water or easily removable milk solids, or milkstone layer shall be regarded as unsatisfactory.

4.3.2.2 Rinse method

Pour 500 ml of sterile rinsing solution into the lid and then into the can. Replace the lid. Lay the can on its side on a clean floor or on a can roller and roll it so that it makes 12 complete revolutions. Allow the can to stand upright for 5 min and then repeat the rolling. Pour the rinse solution from the can into the lid and then into the original bottle. In transferring the solution to the original bottle, collect as much as possible of the 500 ml.

The solution should be examined immediately. If this is not possible, any delay shall be kept to a minimum and the sample shall be cooled quickly to not more than 4 °C and maintained between 0 and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 to 10 h).

NOTE — The rinsing solution should contain sodium thiosulfate or other suitable inactivator as indicated in notes 1 and 3 to 4.2.5.

4.3.3 Washed milk-collection tankers

4.3.3.1 General

The method outlined is designed to give information on the condition of tankers immediately after washing and immediately prior to re-use. Areas to be examined include lid, hose, valves and surrounding pipework as well as the barrel itself.

The examination should be undertaken not less than 30 min and within 1 h after washing. A visual inspection should be made as outlined in 4.1.

4.3.3.2 Swab method

See 4.2.6.

4.3.4 Washed milk bottles

4.3.4.1 General

The method outlined is designed to give information on the condition of bottles immediately after washing and immediately before re-use.

4.3.4.2 Sampling

Select bottles for examination immediately after washing and immediately before re-use. Close with suitable sterile closures. After closing, take the bottles to the laboratory as soon as possible.

4.3.4.3 Rinse method

Add 20 ml of sterile rinsing solution to each of the bottles and replace the closure. Use this quantity irrespective of the size of the bottle. Where bottles are taken from a hot section of a machine for special purposes, fit them with a suitable sterile closure and allow to cool before rinsing. Hold the bottle horizontally in the hands and rotate gently 12 times in one direction so that the whole of the internal surface is thoroughly wetted. Allow the bottle to stand for not less than 15 min and not more than 30 min and again gently rotate 12 times so that the whole of the internal surface is thoroughly wetted.

Return the rinse to its previous container. The solution should be examined immediately. If this is not possible, any delay shall be kept to a minimum and the sample shall be cooled quickly to not more than 4 °C and maintained between 0 and 4 °C until examined (in any case within 24 h of sampling, but preferably within 6 to 10 h).

NOTE — The rinsing solution should contain sodium thiosulfate or other suitable inactivator as indicated in notes 1 and 3 to 4.2.5.

4.4 Sampling procedures for air

4.4.1 Sampling for airborne micro-organisms in dairy plants involves collecting samples in air pathways by which organisms may be introduced into processing equipment. Samples may be taken as follows:

- a) at openings in equipment subject to potential contamination from organisms transported by air currents;
- b) at selected points for testing the quality of air in the room, for example where containers are filled with products;
- c) in areas where employees are concentrated.

Because of air turbulence during operating hours, sampling by volumetric methods will be more effective and dependable than use of the sedimentation technique.

4.4.2 The sampling methods used could be

- a) suction of a known volume of air through a suitable filter, buffer solution or nutrient broth;

NOTE — Air sampling equipment is commercially available. A controlled and known volume of air is made to impinge upon an agar surface.

- b) exposure of agar plates for a certain period of time.

The objective of both methods is to determine the number of organisms in the filter, buffer solution or nutrient broth or on the plates. The sampling time for all methods of collection is usually standardized at 15, 30 and 60 min, the duration being determined by experience or estimation. Samples may be taken monthly to detect specific micro-organisms unless more frequent sampling is necessitated by emergency conditions or suspected contamination.

4.5 Sampling procedures for water and aqueous solutions other than those added to the product

4.5.1 Sampling of water and aqueous solutions should be carried out while the material is in motion, and care shall be exercised to ensure that the samples are representative.

Not less than 2 litres shall be taken. The sample shall be placed in a suitable clean, airtight container, reserved solely for water samples, which shall be of such a size that it is completely filled by the sample. Care shall be taken to avoid the risk of contaminating the contents in any way.

4.5.2 All cleansing solutions should be tested before use in order either to confirm that the concentration is correct or to calculate any adjustments needed to obtain this concentration. Routine monitoring of the amount of detergent which it is necessary to add will indicate any abnormal demand which could be the result of heavy deposits on plant surfaces.

NOTE — If cleansing solutions are recovered or re-used, care should be taken to avoid microbiological contamination.

4.5.3 Temperatures of cleansing solutions should be checked during each cleansing cycle. Moreover, the duration of the cleansing cycles should be checked at regular intervals.

4.5.4 The varieties of conditions under which collection of water and solutions is performed makes it impossible to prescribe a fixed procedure of sampling. In general, the sampling procedure should take account of the tests to be performed.

4.5.5 The sample container should be rinsed two or three times with the material being collected before filling.

4.6 Sampling procedures for raw materials and products

Methods of sampling for milk and milk products as specified in ISO 707 should also be consulted.

4.6.1 One method of assessing the hygienic state of dairy plant is to check the bacteriological condition of the raw materials and products. If this condition, taking into account the nature of the plant and the experience of management, indicates contamination, it is good evidence that the plant is insanitary at some point before the sampling point. All processes can be split into blocks of equipment. If three consecutive blocks of equipment A, B and C are examined by taking samples before and after each block, and the sample between B and C is contaminated whilst that between A and B is not, contamination has occurred in B.

NOTE — For example the manufacture of cream might include milk storage, heating, separation, cream pasteurization, cooling, and cream storage, with transfer operations between the stages. A sample taken from the storage tank which showed large numbers of organisms normally destroyed by heating would indicate contamination between pasteurization and storage. Further sampling between these points could then show which item of plant was at fault.

4.6.2 The raw material at the start of production is milk. The milk is sampled from storage tanks at regular intervals. Sometimes it is of advantage or legally required to test milk from each supplier, taking samples at specified intervals.

4.6.3 Appropriate times for checking a product will be immediately before manufacture, during manufacture of the product prepared or in course of preparation, and after finishing processing. In general, it is sensible to provide sampling points for product removal as follows:

- a) road tanker, storage tank and balance tank;
- b) valves and/or places in the pipe system;
- c) after heat treatment;
- d) after addition of food ingredients and additives;
- e) after contamination with air may have occurred;
- f) after a prolonged residence time (more than about 2 h);
- g) final packed product.

4.6.4 It is of special importance to take samples of the first product to emerge from the plant (after a cleansing sequence or other interruption). The difference between the first product and the last product in a run can also indicate how often cleansing is needed. Accordingly, arrangements should be made to sample the product at these times.

4.6.5 Sampling of liquid products should be performed while the material is in motion. When taking samples from an open container, it is necessary to agitate the product until it is homogeneous.

NOTE — Sampling in-line may conveniently be performed using stainless steel nipples fitted with sterile rubber serum caps and collecting samples using disposable plastic syringes inserted through the rubber caps.

5 Inspection and sampling report

The inspection and sampling report shall contain the following information:

- a) a reference to this International Standard;
- b) a reference to the method(s) used;
- c) if applicable, precise identification of the sample;
- d) any operations not specified in this International Standard or regarded as optional;
- e) the date and place of inspection and sampling.

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